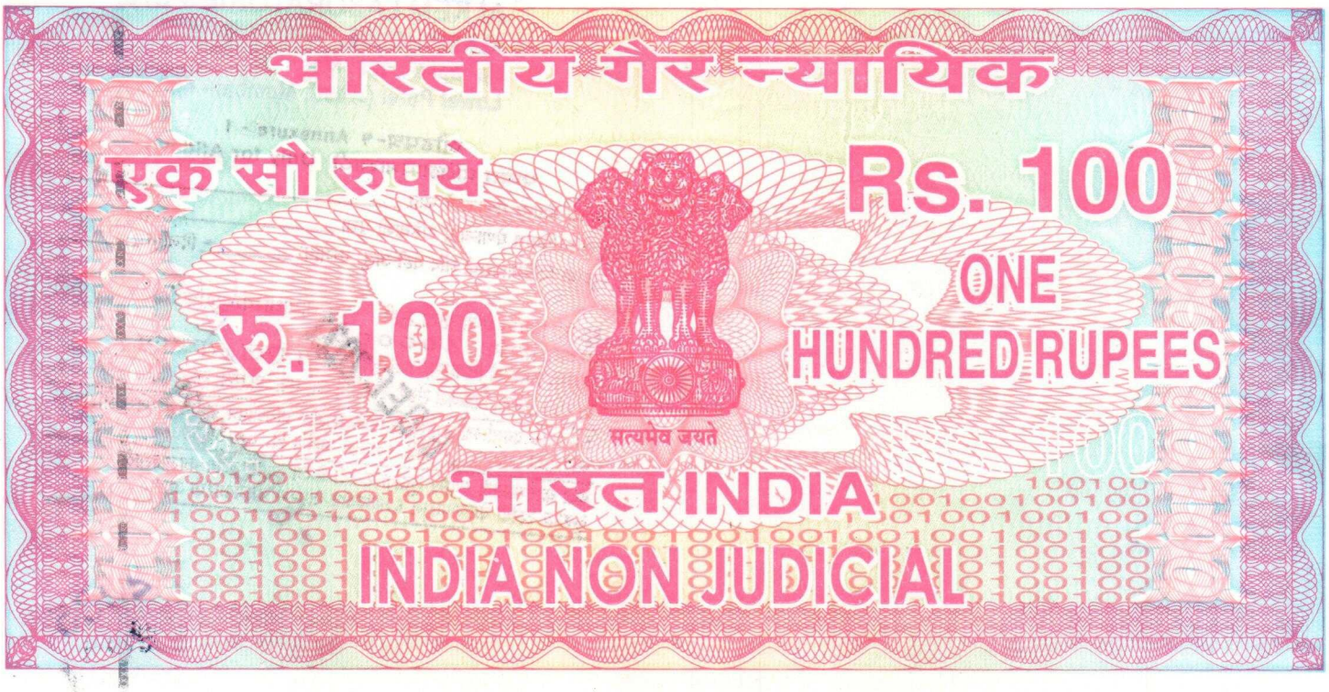

महाराष्ट्र MAHARASHTRA ◐ 2021 ◐ ZH 541157

प्रधान मुद्रांक कार्यालय, मुंबई.
प.मु.वि.क्र. ८०००००६
- 2 DEC 2021
सक्षम अधिकारी

CLINICAL TRIAL AGREEMENT

This contract (hereinafter "**the Contract**") is made as of the **20-12-2021** (hereinafter "**the Effective Date**"), by and among:

Dr Raghavendra S K, Assistant Professor, Department of Community Medicine, Adichunchanagiri Hospital & Research Centre, B G Nagara-571 448, Nagamangala Taluk, Mandya, Karnataka, India.

Hereinafter "the **INVESTIGATOR**",

AND

Adichunchanagiri Hospital & Research Centre, B G Nagara-571 448, Nagamangala Taluk, Mandya, Karnataka, India.

Hereinafter "the **INSTITUTION**" study site

AND

Alkem Laboratories Limited, having its registered office at Alkem House, Senapati Bapat Marg, Lower Parel, Mumbai 400013, India.

Hereinafter "the **SPONSOR**"

Initials INVESTIGATOR Initials INSTITUTION Initials SPONSOR

ALKEM LABORATORIES LIMITED MUMBAI INDIA

ALKEM LABORATORIES LTD.
ALKEM HOUSE,
Senapati Bapat Marg,
Lower Parel (West), Mumbai - 400 013.

जोडपत्र-१ Annexure - I
फक्त प्रतिज्ञापत्रासाठी Only for Affidavit

मुद्रांक विकत घेणाऱ्याचे नाव _____
मुद्रांक विकत घेणाऱ्याचे राहिवाशी पत्ता _____
मुद्रांक विक्रिबाबतची नोंद वही अनु. क्रमांक _____ दिनांक _____

मुद्रांक विकत घेणाऱ्याची सही परवानाधारक मुद्रांक विक्रित्याची सही
परवाना क्रमांक : ८०००० एल सनद्धाण
मुद्रांक विक्रीचे ठिकाण/पत्ता ३/२७२, बेस्ट बिल्डिंग हाउस, एस.बी.एस. मार्ग, फोर्ट, मुंबई - ०१.
शासकीय कार्यालयासाठी/न्यायालयासमोर प्रतिज्ञापत्र करण्यासाठी मुद्रांक खरेदी आवश्यकता नाही. (शासन आदेश दि. ०१/०३/२००४) नुसार
ज्या कारणासाठी व्यक्तीने मुद्रांक खरेदी केला त्या व्यक्ती व कारणासाठी मुद्रांक खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे.

6 DEC 2021
6 DEC 2021

2035

The INVESTIGATOR, the INSTITUTION and the SPONSOR are hereinafter individually referred to as a "**Party**" or collectively referred to as the "**Parties**".

WITNESSETH:

WHEREAS, the SPONSOR is to perform a clinical trial (hereinafter the "Study") to evaluate its product FDC (Metformin+Sitagliptin+ Pioglitazone (hereafter the "Investigational Product") in accordance with a protocol of SPONSOR entitled A Phase 3, multicenter, randomized, double-blind, double-dummy, parallel-group, active-controlled study to compare the efficacy and safety of a fixed dose combination of Metformin hydrochloride 1000 mg SR, Sitagliptin phosphate 100 mg and Pioglitazone 15 mg tablets versus Janumet XR CP (Combipack of Metformin hydrochloride 1000 mg SR and Sitagliptin phosphate 100 mg) in patients with Type 2 Diabetes Mellitus (T2DM) [ALK24-MSP1] and its amendments (hereinafter collectively the "Protocol"),

AND WHEREAS, the INSTITUTION and the INVESTIGATOR having each reviewed the Protocol for the Study, the Clinical Investigator Brochure and sufficient information regarding the Investigational Product to evaluate their interest in participating in the Study, wish to participate in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study.

In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into the Contract, which provisions shall apply in compliance with those of the Protocol.

ARTICLE 1. PROTOCOL

The Study shall be performed in strict compliance with the Protocol a copy of which has been provided and signed by the INVESTIGATOR, INSTITUTION and SPONSOR, as such Protocol is submitted to the registered Institutional Ethic Committee ("**IEC/IRB**") for favorable opinion/ approval and as the Protocol may be amended from time to time thereafter.

Any amendment to the Protocol shall be notified to the relevant IEC/IRB according to regulation & guidelines mentioned in section 3.1. All the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of the Contract.

To the extent that there may be any inconsistency between this Contract and the Protocol, this Contract shall control, except with respect to medical or clinical matters for which the provisions of the Protocol shall take precedence.

ARTICLE 2. STUDY SITE

The Study shall be performed at the INSTITUTION (hereinafter the "**Study Site**"). The INVESTIGATOR and the INSTITUTION shall be responsible for obtaining any authorization from the representatives of the Study Site where the Study is performed.

For the avoidance of doubt, the sums paid under Exhibit 1 of the Contract to the INVESTIGATOR and/or the INSTITUTION involves compensation for the performance of the Study carried out at the Study Site.

The INVESTIGATOR hereby represents, warrants and covenants that he/she has and shall maintain all necessary authorizations from the Study Site representatives to perform the Study and that he/she shall take responsibility for the payment of any cost incurred by the Study Site in connection with the Study, the amount and terms of which shall be directly and exclusively handled by the INVESTIGATOR and the Study Site.

ARTICLE 3. COMPLIANCE

3.1 The Study shall be performed in accordance with (i) the Protocol (ii) all applicable Central, State and Local laws, rules and regulations in India including the Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research and the Indian GCP Guidelines, (iii) the Guideline for Good Clinical Practice of the International Conference on Harmonization (hereinafter the "**ICH–GCP**"), (iv) the principles laid down by the 18th World Medical Assembly (Helsinki, 1964) and all applicable amendments laid down by the World Medical Assemblies, and (v) the specific procedures provided by the SPONSOR applicable for conducting the Study.

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3.2 The INVESTIGATOR and the INSTITUTION shall ensure that all procedures defined in the Protocol are complied with, so that all data coming from the Study Site are reliable and have been processed correctly (especially the randomization lists, and the blind character of the Study as the case may be) and will ensure that the content of the case report form (CRF)/electronic case report form (e-CRF) will accurately reflect source documents.

3.3 The INVESTIGATOR and the INSTITUTION shall submit CRF/e-CRFs to the SPONSOR.

ARTICLE 4. TERM

This Contract is being entered into force from the Effective Date and shall expire upon receipt by the SPONSOR of all data generated by the INVESTIGATOR and after completion of the close-out visit for the Study Site.

The Parties estimate that the whole Study will take approximately 12 months from the first visit of the first Subject to the last visit of the last Subject.

ARTICLE 5. ITEMS SUPPLIED BY THE SPONSOR

5.1 The SPONSOR shall provide the INVESTIGATOR and/or the INSTITUTION with all necessary information, documents and materials, including but not limited to :

- the Investigator's Brochure (IB)
- the Protocol,
- the Informed Consent Form
- the CRF/e-CRF
- the Investigational Product manufactured in accordance with the applicable regulations and/or the Good Manufacturing Practice (GMP), suitably packaged and labeled and in sufficient quantity to conduct the Study.

5.2 The INVESTIGATOR, the Collaborators and the INSTITUTION shall use the information, documents and Investigational Product provided by the SPONSOR, solely for the purpose of the Study or to fulfill their own regulatory obligations, to the exclusion of any use for their own or for a third party's account.

For the purpose of the Contract, the term "Collaborator(s)" shall mean any person involved in the Study including but not limited to research associates, sub-investigators, biologists, assistants and nurses.
Unless otherwise instructed by the SPONSOR or required by applicable laws and regulations, the information, documents and Investigational Product shall be returned or made available to the SPONSOR upon completion of the Study.

The INVESTIGATOR shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATOR shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

The Investigational Product will not be released until the SPONSOR has received a copy of the written and dated approval/opinion of the IEC/IRB and DCGI for the study.

5.3 The INVESTIGATOR / INSTITUTION or its designee shall ensure that an accurate record of the quantity of Investigational Product received and dispensed to each patient is maintained. The INVESTIGATOR/INSTITUTION shall ensure that the Investigational Product is stored and dispensed in accordance with the SPONSOR's specifications and applicable laws and regulations.

5.4 The INVESTIGATOR/INSTITUTION agrees to take responsibility for the safeguarding of such materials and to notify SPONSOR promptly in case of any loss, damage or failure of these materials.

5.5 Upon termination or completion of the Study, all unused Study Drug, compounds, drugs devices, case report forms, whether or not completed, and other related materials that were furnished to the INVESTIGATOR/INSTITUTION by or on behalf of the SPONSOR shall be returned to the SPONSOR.

ARTICLE 6. SUBJECTS' RECRUITMENT

6.1 The INVESTIGATOR has estimated that he/she may require to recruit a maximum of 30 (Thirty) Subjects (the "**Subjects**"), within four months of commencement of the Study. This target of recruitment can be increased only upon written agreement of the SPONSOR. In addition, SPONSOR may establish a threshold number of Subjects and rate of accrual of Subjects (e.g, x Subjects per day/week/month) to allow

for appropriate monitoring of the Study and will communicate this information to the INVESTIGATOR. The INVESTIGATOR undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the SPONSOR.

6.2 A minimum of two patients must be enrolled within two months of initiating the Study at the STUDY SITE. If no subjects are enrolled over a period of three months, the SPONSOR may decide at its discretion to discontinue the Study at the STUDY SITE.

6.3 The SPONSOR reserves the right to request the INVESTIGATOR to limit the recruitment of further Subjects or cease the recruitment, notably in case the recruitment target for the Study has been reached. In such case, the SPONSOR shall inform the INVESTIGATOR to stop the recruitment of any subject who has not yet signed informed consent. The INVESTIGATOR shall upon receipt of the written notice stop immediately further recruitment of Subjects. Payments shall only be made according to the number of Subjects recruited up to the date of receipt of the notice by indicating no further recruitment. The SPONSOR will not take any responsibility and make any payment for the Subjects recruited after this date.

ARTICLE 7. CONSENT OF THE SUBJECTS

7.1 Before any Subject's participation in the Study, the INVESTIGATOR shall fully inform any subject and/or, as the case may be, her/his legal representative, in language understandable to them, of all pertinent aspects of the Study in accordance with the requirements stipulated under Indian laws/regulations (Article 3.1).

7.2 The INVESTIGATOR shall ensure that all Subjects participating in the Study and/or their legal representative (i) have received a copy of the Subject information leaflet, and (ii) have expressed their prior consent by signing the informed consent form, in such format as approved by DCGI or Other Authority, without the undue influence or coercion of any person directly involved in the Study, and only after having been duly informed.

7.3 The INVESTIGATOR &/ INSTITUTION shall ensure that the entire informed consent process referred to in Article 7.2 above be video recorded if the same is applicable as per local regulations and/or made applicable by Institutional Ethics Committee. The INVESTIGATOR &/ INSTITUTION should ensure that the confidentiality of the recorded files is appropriately maintained.

ARTICLE 8. MONITORING OF THE STUDY

8.1 The SPONSOR shall appoint monitor(s) from their end or from Clinical Research Organization (CRO), bound by a professional confidentiality obligation, who will work with the INVESTIGATOR and the INSTITUTION to ensure proper conduct of the Study (hereinafter the "**Monitor(s)**"). The INVESTIGATOR and the INSTITUTION agrees to fully cooperate with the SPONSOR's monitoring procedures and maintain all necessary patient information

8.2 The Monitor shall be entitled to visit the Study Site and be regularly informed about the performance of the Study and shall collect all the documents and information about the Study in accordance with the Protocol and the ICH-GCP. He/she shall have access to all records on the Subjects and all information pertaining to the Study, as well as, copies thereof, if needed. In case if onsite monitoring is not be possible, monitor can perform remote monitoring where site can share all the documents on secure server and monitor can review the same while maintaining the confidentiality of subjects

ARTICLE 9. DUTY OF INFORMATION

The INVESTIGATOR and/or the INSTITUTION shall immediately inform the SPONSOR, Licensing Authority & Ethics Committee of any serious adverse event ("**SAE**") or other events as defined in the Protocol.

ARTICLE 10. FINANCIAL TERMS AND CONDITIONS

10.1 In consideration for the proper performance by the INVESTIGATOR and the INSTITUTION of their obligations under the Contract, the SPONSOR shall compensate the INVESTIGATOR and/or the INSTITUTION in compliance with the payment terms defined in Exhibit 1. Payment terms may be modified only upon prior written consent of the Parties. Likewise, non-emergency additional tests or services (tests or services non-required by the Protocol or performed in excess of Protocol requirement) shall not be reimbursed hereunder without the prior written consent of the SPONSOR.

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ARTICLE 11. CONFIDENTIALITY AND RESTRICTED USE

11.1 All information disclosed or provided by the SPONSOR or produced during the Study, including but not limited to the Protocol, the Investigator's brochure and CRF/e-CRF, the results obtained during the course of the Study, the financial terms of the Contract (hereafter the "**Confidential Information**"), is confidential. The INVESTIGATOR and the INSTITUTION agree to keep confidential and not to disclose the Confidential Information to any third party without the prior written approval of the SPONSOR. The INVESTIGATOR and the INSTITUTION shall use the Confidential Information solely for the purposes of the Study.

11.2 Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects, the INVESTIGATOR, the INSTITUTION and the Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use. The INVESTIGATOR shall inform the Collaborators of the confidential nature of the Study and will only provide them with the Confidential Information that is strictly necessary for the accomplishment of their acts.

11.3 Confidential Information shall not include information that: (1) is at the time of disclosure, or thereafter becomes, publicly available through no fault of the INVESTIGATOR or the INSTITUTION; (2) is disclosed to the INVESTIGATOR or to the INSTITUTION by a third party entitled to disclose such information in a non-confidential manner; (3) is known to the INVESTIGATOR or to the INSTITUTION prior to disclosure under this Contract, as shown by the INVESTIGATOR's or the INSTITUTION's prior written records; (4) can be documented to have been independently developed by Study Site's personnel without reliance on Confidential Information; or (5) is required by applicable law to be disclosed, provided that the INVESTIGATOR or the INSTITUTION give the SPONSOR prompt notice of such fact so that it may obtain a protective order or other appropriate remedy concerning any such disclosure, cooperate fully with the SPONSOR in connection with its efforts to obtain any such order or other remedy, and disclose, where disclosure is necessary, only the information legally required to be disclosed.

11.4 The obligations of confidentiality and restricted use contained herein are applicable during the term of the Contract and shall survive for 10 (ten) years from its date of termination or expiry whichever is later.

ARTICLE 12. RECORD RETENTION

The INVESTIGATOR and the INSTITUTION through the Study Site shall retain and preserve one (1) set only of all original data generated in the course of the Study for 5 years from the date of the last visit of SPONSOR to the Study Site after the Study is completed ("**Retention Period**").

The SPONSOR must be informed in writing of any change of address or relocation of the Study files and of the INVESTIGATOR /the INSTITUTION during this period.

Following the Retention Period, as instructed by the SPONSOR, the INVESTIGATOR and/or the INSTITUTION will either forward such records to the SPONSOR at the SPONSOR's expense, retain such records for a reasonable additional charge to be mutually agreed , or destroy the records, and send the SPONSOR proof of such destruction. Subject files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations.

ARTICLE 13. DATA PROTECTION

13.1 The Subject data, the INVESTIGATOR's data, the INSTITUTION's data and Collaborators' data, which may be included in the SPONSOR's databases, shall be treated by the Parties in compliance with all applicable laws and regulations.

13.2 The SPONSOR also collects specific data regarding the INVESTIGATOR and the Collaborators which may be included in the SPONSOR's databases, shall be treated by both Parties in compliance with all applicable laws and regulations.

13.3 When archiving or processing data pertaining to the INVESTIGATOR, the Collaborators, the INSTITUTION and/or the Subjects, the SPONSOR shall take all appropriate measures to safeguard and prevent access to this data by unauthorized third party.

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ARTICLE 14. PUBLICATIONS AND COMMUNICATIONS

14.1 The INVESTIGATOR and the INSTITUTION undertakes not to make any publication or release pertaining to the Study and/or results of the Study without the SPONSOR's prior written consent, being understood that the SPONSOR will not unreasonably withhold its approval.

14.2 The INVESTIGATOR and the INSTITUTION shall not use the name(s) of the SPONSOR and/or of its employees in advertising or promotional material or publication without the prior written consent of the SPONSOR. The SPONSOR shall not use the name(s) of the INVESTIGATOR, the INSTITUTION and/or the Collaborators in advertising or promotional material or publication without having received their prior written consent(s).

14.3 The SPONSOR has the right at any time to publish the results of the Study.

ARTICLE 15. PROPERTY RIGHTS

15.1 All Confidential Information, documents, materials, Investigational Product and equipment provided by the SPONSOR (hereinafter collectively "**Information**") are and shall remain the sole and exclusive property of the SPONSOR.

The INVESTIGATOR and INSTITUTION shall not and shall cause the Collaborators not to mention any Information in any application for a patent or any other intellectual property rights whatsoever.

15.2 All the results, data, documents, discoveries and inventions which arise directly or indirectly from the Study in any form, shall be the immediate and exclusive property of the SPONSOR or its designee. For this purpose, the INVESTIGATOR, the Collaborators and the INSTITUTION presently assign to the SPONSOR (or its designee) all intellectual property rights (including all patents, copyrights, databases and any application or right to apply for registration of any of those rights) which may arise directly or indirectly from the Study and all existing or future materials created in relation to the Study.

15.3 The SPONSOR may use all the results at its own discretion, without any limitation to its property right (territory, field, continuance, etc.), and without any additional payment. The SPONSOR shall be under no obligation to patent, develop, market or otherwise use the results of the Study, issued under this Contract.

ARTICLE 16. LIABILITY – INDEMNIFICATION – INSURANCE

16.1 The SPONSOR agrees that it has subscribed to a liability insurance policy to cover its liability as required by applicable law. The SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a certificate of insurance.

16.2 The insurance subscribed to by the SPONSOR does not release either the INVESTIGATOR or the INSTITUTION from their obligation to maintain their own liability insurance policies.

16.3 The SPONSOR agrees to indemnify, hold harmless and defend the INVESTIGATOR, the INSTITUTION, and the Collaborators ("**Indemnitees**") from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the Investigational Product or the performance of any procedure required under the Protocol as per Indian laws, except to the extent such claim or suit is attributable to:

(1) a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the SPONSOR regarding the administration of the Investigational Product or the performance of any required procedure;

(2) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or

(3) the negligence or wilful malfeasance of the Indemnitees.

The SPONSOR shall have no obligation under this Article, however, unless: (i) the SPONSOR is promptly notified of any such claim or suit; (ii) the Indemnitees cooperate fully in the handling thereof; and (iii) the SPONSOR has sole control over the disposition of such claim or suit, including the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability on the part of the Indemnitees without their prior written consent, which consent shall not be unreasonably withheld.

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ARTICLE 17. AUDITS AND INSPECTIONS

17.1 For the purpose of ensuring compliance with the Protocol, Good Clinical Practice and applicable regulatory requirements, the INVESTIGATOR and the INSTITUTION shall permit audits by or on behalf of the SPONSOR and inspections by applicable regulatory authorities.

The INVESTIGATOR agrees to allow the auditors and/or inspectors to have direct access to his/her Study records and to Subjects files for review, being understood that this personnel is bound by professional secrecy, and as such will not disclose any personal identity or personal medical information.

17.2 The INVESTIGATOR and the INSTITUTION shall devote their best efforts to facilitate the performance of any audit and inspection and shall give to the SPONSOR or to any person designated by the SPONSOR access to all necessary facilities, data and documents.

17.3 As soon as either the INVESTIGATOR or the INSTITUTION is notified of a future inspection by the authorities, they shall inform the SPONSOR and authorize the SPONSOR to participate to this inspection. The information that arises from the inspections by the regulatory authorities will be immediately communicated by the INVESTIGATOR and/or INSTITUTION to the SPONSOR.

17.4 The INVESTIGATOR and the INSTITUTION shall take appropriate measures required by the SPONSOR to take corrective actions without delay in order to solve all problems found during the audits or inspections.

17.5 It is expressly agreed between the Parties that the SPONSOR will not compensate the INVESTIGATOR and/or the INSTITUTION for the audits and inspections and that the assistance and availability of the INVESTIGATOR or the INSTITUTION for the audits and inspections, if any, is included in the amount mentioned in Exhibit 1.

17.6 The rights and obligations under this Article shall remain in effect for a period of five (5) years after the end of the Study.

ARTICLE 18. TERMINATION OF THE CONTRACT

This Contract may be terminated: (1) by a mutual written consent of the SPONSOR, INVESTIGATOR and the INSTITUTION on immediate basis; or (2) by the SPONSOR upon serving thirty (30) days prior written notice to the INVESTIGATOR and the INSTITUTION.

In the event this Contract is terminated, the SPONSOR will be responsible for compensating INVESTIGATOR and/or the INSTITUTION for actual activities performed hereunder in accordance with the terms of this Contract and reasonable non-cancellable expenses incurred prior to notice of termination if such expenses were required under the Protocol and contemplated within Exhibit 1. Any funds paid in advance will be prorated and any excess funds will be returned to the SPONSOR. The INVESTIGATOR shall provide the SPONSOR with all documentation required by the Protocol and applicable laws and regulations and any equipment provided by the SPONSOR in connection with the Study no later than ninety (90) days after the completion or early termination of the Contract.

The terms and conditions of Articles 11, 13, 14, 15, 19 shall survive the expiration or earlier termination of this Contract.

ARTICLE 19. DEBARMENT AND SENTENCING FOR MALPRACTICE

The INVESTIGATOR and the INSTITUTION represent and warrants that neither he/she nor any Collaborators /INSTITUTION involved in conducting the Study nor any member of the staff of the INSTITUTION, has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct.0.

The INVESTIGATOR shall immediately notify the SPONSOR should he/she or any Collaborators involved in conducting the Study, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Contract and during the twelve months following the expiration or termination of the Contract.

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ARTICLE 20. CONFLICT OF INTERESTS AND FINANCIAL DISCLOSURE

The INVESTIGATOR shall ensure that he/she and the Collaborators involved in this Study at the INVESTIGATOR's Study Site provide the SPONSOR with the appropriate financial disclosures required for compliance with DCGI, on such forms as the SPONSOR may supply or approve.

ARTICLE 21. MISCELLANEOUS

21.1 The Protocol, the Contract and all others documents exchanged between the Parties constitutes the whole undertaking of the Parties. All appendices attached hereto shall be deemed to be incorporated herein.

21.2 Any work performed by the INVESTIGATOR, the Collaborators and/or the INSTITUTION under this Contract shall be considered to be performed by them as independent contractors and not as employees, partners or agents of the SPONSOR. No Party shall have the authority, either express, implied or apparent, to bind the other Party, except to the extent that same may be consistent with the performance of that Party's obligations in accordance with the terms of this Contract.

21.3 Except as otherwise expressly mentioned hereinabove, any notification shall be made by mail or fax.

21.4 If either Party is prevented from fulfilling its obligations in accordance with the terms of this Contract due to force majeure (as defined by competent law and/or competent court), this Party shall be released from performance to the extent that it is so prevented from doing so for the duration of the intervening circumstances. The Party wishing to claim relief on the grounds of the said circumstances shall notify the other Party in writing without delay on the intervention or cessation thereof. The Party so prevented from fulfilling its obligation shall devote its best endeavors to remove or avoid the impediment as soon as possible. If the Party is prevented from fulfilling its obligations under this Contract due to force majeure for a period exceeding two (2) running months, each Party shall have the right to terminate this Contract by registered mail with acknowledgment of receipt. The termination will become effective forthwith.

21.5 No indulgence granted by either Party to the other in relation to any term hereof shall be deemed a waiver of such term or prejudice the later enforcement of that or any other term hereof.

21.6 Should a provision of this Contract in any manner whatsoever contravene any applicable laws and regulations, such provision shall be deemed to be severable and shall not affect any other provision of this Contract, nor affect the enforceability of those remaining provisions which are not in contravention of any law and regulation.

21.7 The Contract is concluded by the SPONSOR intuitu personae. Hence, the INVESTIGATOR and the INSTITUTION shall not be allowed to transfer totally or partially the obligations the SPONSOR charged them with, nor to subcontract them without the prior written consent of the SPONSOR. The INVESTIGATOR and the INSTITUTION shall, where applicable, transmit to the Collaborators the Contract and shall cause them to abide by its terms and conditions. The SPONSOR may transfer this Contract to a successor in interest to its business by reason of any merger, acquisition, partnership, license agreement or otherwise, provided that the assignee is subject to the terms and obligations provided in this Contract.

21.8 This Contract constitutes the entire agreement between the Parties relative to the subject matter hereof and supersedes all representations, warranties, agreements or undertakings previously made relative to such subject matter, and no such representations, warranties, agreements or undertakings shall be any force and effect unless contained herein. No variation of any terms and conditions of this Contract will be binding upon the Parties unless committed in writing and signed by them respectively.

21.9 This Contract shall be governed by the laws of India. Prior to taking any legal action, the Parties shall endeavor to settle by amicable arrangement any disputes arising between them regarding this Contract. Should the Parties fail to reach an amicable settlement, the Parties agree to submit to the exclusive jurisdiction of the courts of Mumbai and they waive any other forum to which they may be entitled by reason of their present or future address or for any other reason.

21.10 No Party may assign or novate its rights, interests, liabilities or obligations under this Contract or any part thereof without the prior written consent of the other Parties, such consent not to be unreasonably withheld or delayed.

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IN WITNESS WHEREOF, the Parties hereto have caused this Contract to be duly executed on their behalf in three counterparts, each of which shall be deemed to be an original, as of the Effective Date.

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Name: Dr. Akhilesh Sharma
Designation: President & Chief Medical Officer

In presence of: Ms. Bhumika Sonavane
Clinical Trial Assistant
28/12/21

INVESTIGATOR

31/12/2021

Name: Dr Raghavendra S K
Designation: Principal Investigator

In presence of:
03/01/2022
Dr. B. G. Sagar
Medical Superintendent

INSTITUTION

3/1/2022

Name : Dr Rajesh Venkataraman
Designation: Head Clinical Trials

DR. RAJESH VENKATARAMAN
Head, Clinical Trials
Adichunchanagiri Hospital & Research Centre
Adichunchanagiri University
B. G. Nagara - 571 448

In presence of:
E. Mohanasundari
Clinical Research Co-ordinator
03/01/2022

EXHIBIT 1

1. The SPONSOR will pay Investigator fees per visit, as per table below for subjects included in accordance with the Protocol and who has completed these visits as per protocol requirement, on monthly or quarterly basis against the invoice raised by INVESTIGATOR .

ALK24-MSP1 STUDY Site Budget			
Visit. No	**Particulars**	**PI grant**	**Patient expense**
1	Screening including run in period	6,000	1000
2	W0	5,000	500
3	W0 (day 1)	5,000	500
4	W4	5,000	500
5	W8	5,000	500
6	W12	6,000	500
7	W16	5,000	500
8	W20	5,000	500
9	W24	6,000	500
Per Patient Grant (A)		**48,000**	**5000**
Additional Grant (B)			
1	Lab Cost	**Actuals**	
2	Institutional Overheads (25%)	12000	
Total (A+B)		**65000**	

The above fees is inclusive of Investigator, coordinator, Nurse, Phlebotomist, Social worker fees including assessment such as physical Examination (including assessment of signs and symptoms associated with COVID-19), vital signs, body weight and any other administrative cost such as OPD fees/hospitalisation fees if required, patient expense (travel, snacks etc), Institutional overhead charges, etc.

2. Ethics Committee fees and local lab charges will be paid on actual basis.

3. A subject is considered as having completed the study when he/she has completed the specified study period, and is evaluated as per the Protocol.

4. Archival fees for 5 years will be Rs. 25,000/-

5. Laboratory tests should be done in an NABL acredidated lab, the expense towards the same shall be reimbursed by the sponsor as per the rate card approved by the sponsor, if done in Central lab sponsor will pay directly to the central lab.

6. In case, if the Site team conducts any specific unscheduled lab investigation for AE and SAE management, the same will be reimbursed by the sponsor, as per the rate card approved by the sponsor.

7. In case of subjects recruited but not having completed the study, the amount to be paid will be calculated according to the fees of the visits actually performed by that subject. No payment will be made for an ineligible subject incorrectly randomized into the study or in case the subject did not complete the study due to negligence, malpractice, breach of protocol, willfully wrong act or omission on the part of the INVESTIGATOR/ INSTITUTION.

8. A sum of Rs 6000/- (Six thousand only) per subject will be paid as investigator fees for upto 20% of screen failure subjects at site, this sum includes investigator fees, patient travel and meals.

9. The investigator fees towards the completed visits shall paid on prorata basis by the SPONSOR in event of drop out or withdrawal.

10. The payment for recruited Subjects will be made to the INSTITUTION upon presentation of the invoices within 45 days as per below payee account details.

ALKEM LABORATORIES LIMITED MUMBAI INDIA

NAME OF PAYEE	
Payment through Cheque:	
Name of Payee:	SACCP CLINICAL RESEARCH
Address of Payee:	Clinical Trial Centre Adichunchanagiri Hospital & Research centre Hospital Block, B G Nagara-571 448.
PAN / TAN Number:	AAAJA2708B
GST No.	29AAAJA2708B1ZU
Payment through wire transfer:	
Beneficiary's Account Name:	SACCP CLINICAL RESEARCH
Beneficiary's Account Number:	8610101031980
Bank Name:	Canara Bank
Bank Address:	Adi-Chunchunagiri Instt of Medical Science branch Bellur, Karnataka-571 448
IFSC:	CNRB0008610

11. Goods and Service Tax shall be added to invoiced amount as per indian tax regulations.

12. All payments made shall be subject to tax deducted at source.

13. The final payment will occur only after:
    - The delivery and review of the final data of the study, provided that they shall be ready for statistical analysis;
    - The completion of all CRF, including resolution of all DRF and after the positive opinion on the part of the SPONSOR regarding their filling;
    - Receipt of all responses to the DRF from the INVESTIGATOR/INSTITUTION;
    - The INVESTIGATOR has to returned all remaining Investigational Product and applicable study material, if any.

ALKEM LABORATORIES LIMITED MUMBAI INDIA

Clinical Trial Details (PDF Generation Date :- Mon, 07 Aug 2023 04:13:46 GMT)

CTRI Number	CTRI/2021/12/038472 [Registered on: 07/12/2021] - **Trial Registered Prospectively**
Last Modified On	27/07/2022
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	A clinical trial to evaluate the safety and efficacy of a fixed dose combination of three antidiabetic drugs versus two antidiabetic drugs in patients with type 2 diabetes mellitus
Scientific Title of Study	A Phase 3, multicenter, randomized, double-blind, double-dummy, parallel-group, active-controlled study to compare the efficacy and safety of a fixed dose combination of Metformin hydrochloride 1000 mg SR, Sitagliptin 100 mg and Pioglitazone 15 mg tablets versus Janumet XR CP (Combipack of Metformin hydrochloride 1000 mg SR and Sitagliptin phosphate100 mg) in patients with Type 2 Diabetes Mellitus (T2DM)

Secondary IDs if Any

Secondary ID	Identifier
ALK24-MSP1 Version 3.0, Dated 6/Sep/2021	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Akhilesh Sharma
Designation	President & CMO
Affiliation	Alkem Laboratories Limited
Address	Alkem Laboratories Limited, Alkem House, Devashish, Adjacent to Matulya centre, Senapati Bapat Marg, Lower Parel Mumbai Mumbai MAHARASHTRA 400013 India Mumbai MAHARASHTRA 400013 India Mumbai (Suburban) MAHARASHTRA 400013 India
Phone	9701346369
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Vinayaka Shahavi
Designation	Deputy General Manager-Clinical Research
Affiliation	Alkem Laboratories Limited
Address	Alkem Laboratories Limited, Alkem House, Devashish, Adjacent to Matulya centre, Senapati Bapat Marg, Lower Parel Mumbai Mumbai MAHARASHTRA 400013 India Mumbai (Suburban) MAHARASHTRA 400013 India
Phone	9833219090
Fax	
Email	vinayaka.shahavi@alkem.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Vinayaka Shahavi
Designation	Deputy General Manager-Clinical Research
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Address	Alkem Laboratories Limited, Alkem House, Devashish, Adjacent to

	Matulya centre, Senapati Bapat Marg, Lower Parel Mumbai Mumbai MAHARASHTRA 400013 India Mumbai (Suburban) MAHARASHTRA 400013 India
Phone	9833219090
Fax	
Email	vinayaka.shahavi@alkem.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Alkem Laboratories Limited, ALKEM HOUSE, “Devashish”, Adjacent to Matulya centre, Senapati Bapat Marg, Lower Parel west, Mumbai 400013

Primary Sponsor

Primary Sponsor Details	
Name	Alkem Laboratories Limited
Address	ALKEM HOUSE, “Devashish”, Adjacent to Matulya centre, Senapati Bapat Marg, Lower Parel west, Mumbai 400013
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Vaishali Pathak	Deoyani Multispecialty Hospital	Lane no.4. Plot no-121, Dhanukar colony, Kothrud, Pune-411038 Pune MAHARASHTRA Pune MAHARASHTRA	9325213624 vaishalipathakdeoyani@gmail.com
Dr Jayashree Shembalkar	Getwell Hospital & Research Institute	20/1, Dr. Khare Marg, Dhantoli Nagpur-440012 Nagpur MAHARASHTRA Nagpur MAHARASHTRA	9881015523 drshembalkar@gmail.com
Dr Mayura Choudhari	Ishwar Institute of Health care	Ishwar heights, 1st floor, plot no.7, gut no 6/1, Beside Punjabi bhawan, Padegoan Aurangabad-431002, Maharashtra, India Aurangabad MAHARASHTRA Aurangabad MAHARASHTRA	9822314268 ishwarhealthcare@gmail.com
Dr Amol Dange	Lifepoint Multispecialty Hospital	145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057 Pune MAHARASHTRA Pune MAHARASHTRA	9823912040 amoldange298@gmail.com
Dr Asish Mondal	Medical College and Hospital	MCH building, 4th floor, 88 college street	9232467518

		kolkata-700073 Kolkata WEST BENGAL Kolkata WEST BENGAL	drasish84@gmail.com
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Dr Onkar Gavali	Lokmanya Multispecialty & accident Hospital	Dhatrak Phata, Mumbai Agra Highway, Nashik, Maharashtra 422207, India Nashik MAHARASHTRA Nashik MAHARASHTRA	9860972279 omkarina_13@yahoo.com
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		Nagpur MAHARASHTRA	
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Dr Suhas Khaire	Noble Hospital	153 A, Magarpatta city road, Hadapsar, Pune 411013, Maharashtra Pune MAHARASHTRA	7045909355 suhaskhaire86@gmail.com
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Dr Sravani Tanna	KIMS-ICON Hospital	32-11-02, Sheela Nagar, BHPV Post, Vishakhapatnam-530012 Visakhapatnam ANDHRA PRADESH	8008926520 sravani.tanna@gmail.com
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Dr S Suresh Kumar	Panimalar Medical College Hospital & Research Institute	Varadharajapuram, Poonamallee, Chennai-600123 Chennai TAMIL NADU	9994197191 sureshgplus@gmail.com
Dr Arif Ahmed Farooqui	Landmark Hospitals	Plot No. 127, Near JNTU metro station, Hydernagar main road, Nizampet, Kukatpally, Hydrabad- 500085, Telangana Hyderabad TELANGANA	9885143487 dr.arifahmedfarooqui@gmail.com
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		380006 Ahmadabad GUJARAT	ravithakkar007@gmail.com
Dr Shaishav Bhanushali	AIMS Hospital	P72, Milap Nagar, Dombivli East - 421203, Maharashtra Thane MAHARASHTRA	9665173631 drshaishavbhanushali@gmail.com
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Dr Ravi Reddy	Kurnool Medical College,	Dept of General Medicine, Budhawara peta, Kurnool, Andrha Pradesh-518002 Kurnool ANDHRA PRADESH	9440294007 dr.ravikaladhar@gmail.com
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Dr Pankaj Kannauje	All India Institute of Medical Sciences,	Gate No. 1, Great Eastern Road, Opposite Gurudwara, AIIMS campus, Tatibandh, Raipur Chattisgarh-492099 Raipur CHHATTISGARH	9752696488 drpankajkannauje@aiimsraipur.edu.in
Dr Dhruvi Hasnani	Rudraksha Multispeciality Hospital	1st floor Rajmandir Complex, Rudraksh hospital road off Barrja flyover, Bareja- 382425 Ahmedabad Ahmadabad GUJARAT	8758485703 dhruvihasnani@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee for clinical trail, AIIMS, Nagpur	Submittted/Under Review	No Date Specified	No
Altezza Institutional Ethics Committee	Approved	26/12/2021	No
Altezza Institutional Ethics Committee	Approved	20/02/2022	No
Clinical Research Ethics Committee	Approved	31/01/2022	No

Ethics Committee Deoyani Multispeciality Hospital	Approved	22/11/2021	No
Ethics Committee Help Hospital Pvt Ltd	Approved	10/01/2022	No
Ethics Committee of Ishwar Institute of Healthcare	Approved	08/01/2022	No
Ethics Committee-Landmark Hospitals	Approved	31/01/2022	No
Getwell Institutional Ethics committee	Approved	30/11/2021	No
Institutional Ethics Committee for Human Research Medical College and Hospital	Approved	08/12/2021	No
Institutional Ethics Committee Kurnool Medical College	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee Post Graduate Institute of Medical Education and Research	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee, AIIMS Raipur	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee, GMC Jalgoan	Approved	09/02/2022	No
Institutional Ethics Committee, Government Medical College, Aurangabad	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee, Government Medical College, Nagpur	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee, KIMS-ICON Hospital	Approved	20/12/2021	No
Institutional Ethics Committee, King George Hospital	Approved	20/12/2021	No
Institutional Ethics Committee,Adichunchanagiri Hospital & Research Centre	Approved	01/01/2022	No
Institutional Human Ethics Committee, Panimalar	Approved	13/12/2021	No
LPR Ethics Committee	Approved	15/11/2021	No
Nirmal Hospital Ethics Committee	Approved	14/12/2021	No
Noble Hospital Institutional Ethics	Approved	12/01/2022	No

Committee			
Rudraksha Hospital Ethics Committee	Approved	27/11/2021	No
Sangini Hospital Ethics Committee	Approved	01/12/2021	Yes
Shree Siddhivinayak Hospital Ethics Committee	Approved	23/12/2021	Yes
Shree Siddhivinayak Hospital Ethics Committee	Approved	23/12/2021	Yes
Shrey Hospital Institutional Ethics Committee	Approved	17/01/2022	No
Shubham Sudhbhawana Superspeciality Hospital Ethics Committee	Approved	27/11/2021	No
Suraksha Ethics Committee	Approved	05/02/2022	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	15/09/2021

Health Condition / Problems Studied

Health Type	Condition
Patients	Type 2 diabetes mellitus without complications

Intervention / Comparator Agent

Type	Name	Details
Intervention	Fixed dose combination of Metformin, Sitagliptin, and Pioglitazone.	Fixed dose combination tablets of Metformin hydrochloride 1000 mg SR, Sitagliptin phosphate 100 mg and Pioglitazone 15 mg. Treatment duration 24 weeks to be taken orally once daily in the morning with food.
Comparator Agent	Combipack of Metformin and Sitagliptin	Metformin hydrochloride 1000 mg SR and Sitagliptin phosphate 100 mg. Treatment duration 24 weeks to be taken orally once daily in the morning with food.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1. Willing to provide voluntary written informed consent and able to comply with the protocol requirements 2. Male or female patients with Type 2 DM of 18 to 65 years of age (both inclusive) 3. Patients who have inadequate glycaemic control to metformin ? 1500 mg/day for at least 6 weeks 4. Patients with HbA1c value between 8.0% and 11.0% (both inclusive)

Exclusion Criteria

Exclusion Criteria	
Details	1. Known hypersensitivity to metformin, sitagliptin or pioglitazone or to any of the excipients of the investigational products 2. Patients with BMI ? 40 kg/m2 3. Laboratory findings measured at screening: a. Creatinine clearance (eGFR) b. Hemoglobin 2.5 X ULN

	g. Serum amylase and/or lipase > 3 X ULN h. Any other screening laboratory value that is clinically significant in the Investigator's opinion precluding patient's participation in the study 4. Patients with Type 1 DM 5. Patients with fasting plasma glucose of > 270 mg/dL 6. Patients with history of macular edema 7. Patients with any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis etc.) 8. Patients with acute conditions with the potential to alter renal function such as dehydration, severe infection, shock, or intravascular administration of iodinated contrast agents 9. Patients who have used corticosteroids for one week or more within 3 months prior to screening 10. Patients with history of acute or chronic cardiovascular or respiratory disease including myocardial infarction, coronary artery disease or shock 11. Patients with cardiac failure or history of cardiac failure (NYHA stages I to IV) 12. Patients with history of bladder cancer or currently presenting with any sign or symptoms suggestive of bladder cancer 13. Positive testing for HIV, hepatitis B (hepatitis B virus surface antigen [HBsAg]) or hepatitis C (hepatitis C virus antibody [HCV Ab]) virology 14. Patients who had suffered from COVID-19 within 8 weeks prior to study drug administration or patients with suspected signs and symptoms of COVID-19/ confirmed novel coronavirus infection (COVID-19) or with history of travel / contact with any COVID-19 positive patient/isolation/quarantine 15. Women of childbearing potential not practicing any acceptable methods of contraception during study. For this study, acceptable and effective methods of contraception for females include: a. Intrauterine device placed at least 6 months prior to the first study dose and agree to follow throughout the study b. Two barrier methods used together (cervical cap, diaphragm, contraceptive sponge, or vaginal spermicide plus a male or female condom) c. Absolute sexual abstinence (no sexual intercourse or genital contact with a male partner) OR d. Females who are surgically sterile OR e. Females who are post-menopausal for at least one year 16. Pregnant or lactating women 17. Patients with clinically significant medical history, vital signs, physical examination as deemed by the investigator or designee

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Centralized
Blinding/Masking	Participant, Investigator, Outcome Assessor and Date-entry Operator Blinded

Primary Outcome

Outcome	Timepoints
Change in HbA1c levels from baseline to Week 24	Baseline to 24 weeks

Secondary Outcome

Outcome	Timepoints
1. Change in body weight from baseline to Week 24 2. Change in fasting plasma glucose (FPG) and	Baseline to 24 weeks

	post-prandial blood glucose (PPG) from baseline to Week 24 3. To evaluate the safety and tolerability of the investigational product
Target Sample Size	**Total Sample Size=**236 **Sample Size from India=**236 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 3
Date of First Enrollment (India)	15/12/2021
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**1 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Closed to Recruitment of Participants
Publication Details	Nil
Brief Summary	This is a Phase 3, multicenter, randomized, double blind, double-dummy, parallel-group, active-controlled study in patients with Type 2 Diabetes Mellitus (T2DM) A total of 236 patients who meet the eligibility criteria will be randomized in the ratio of 1:1 to receive either test product or reference product for 24 weeks The total study duration will be approximately 12 months considering about 06 months of recruitment period and 6 months of study period (4 weeks of screening period which include 2 weeks of run-in period and 24 weeks of treatments period) **Screening period:** 4 weeks (including 2 weeks of run-in period) **Treatment period:** IT will last for 24 weeks **End of study (EOS) assessment:** EOS assessment will be performed at week 24 or at the time of early discontinuation or withdrawal of the patient The primary and secondary objectives of this trail are as follows: - **Primary efficacy endpoint:** Change in HbA1c levels from baseline to Week 24 **Secondary efficacy endpoint(s)**: Change in body weight from baseline to Week 24 Change in fasting plasma glucose (FPG) from baseline to Week 24 Change in post-prandial blood glucose (PPG) levels from baseline to Week 24 **Safety endpoint(s):**

Treatment emergent serious and non-serious adverse events (AEs) during the study

Alteration in clinical laboratory parameters during the study